UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)(KMW)**

PLAINTIFFS' BRIEF IN SUPPORT OF *DAUBERT* MOTION TO PRECLUDE OPINIONS OF DEFENSE EXPERT LEE-JEN WEI, PH.D.

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PRELIMINARY STATEMENT

Lee-Jen Wei, Ph.D., a biostatistician retained by Defendants, submitted a twenty-four page report disputing general causation, *i.e.*, whether the use of Valsartan that is contaminated with NDMA and/or NDEA is capable of causing cancer – contrary to the scientific consensus that NDMA and NDEA are probable human carcinogens. Dr. Wei was tasked by the Defense to assess the opinions of Dr. Madigan, who provided a report on behalf of the Plaintiffs. Dr. Madigan analyzed the results of NDMA/NDEA dietary and occupational exposure studies in order to infer the carcinogenicity of NDMA and/or NDEA, therefore, Dr. Wei was tasked with the same. Additionally, Dr. Madigan computed the mean "lifetime cumulative exposure" (LCE) of NDMA for each study he relied on, which Wei was also asked to assess. Wei provided contrary opinions to each; however, his opinions are unreliable.

Throughout his deposition, Dr. Wei demonstrated that his opinions are not reliable for two main reasons: they are not based on reliable principles and methods, and they are based on preconceived notions about the litigation. Therefore, Dr. Wei's entire opinion, or alternatively, portions of the testimony, should be excluded.

STATEMENT OF FACTS

Dr. Wei fails to grapple with strong evidence from numerous reputable health organizations, including the Environmental Protection Agency (EPA), World Health Organization (WHO), and the International Agency for Research on Cancer (IARC) classifying NDMA as probable human carcinogen. Despite this information, Dr. Wei opined that there is not enough evidence to say whether NDMA is associated with cancer in humans. (09/14/21 Deposition of Lee-Jen Wei (hereinafter "Wei Dep (Day 1)" (attached hereto as **Exhibit 1**)), at 248:1-11). However, Dr. Wei is not qualified to give that opinion.

Prior to this case, Dr. Wei knew little to nothing about NDMA or NDEA, and made no attempt to educate himself on its properties, or the levels which are contained in Valsartan. Despite the fact that Dr. Madigan relied on and cited to internal documents produced by Defendants to determine the amount of NDMA in Valsartan, Dr. Wei did not review these or similar documents, he could not provide an estimated level of NDMA in the product, and he weakly explained that he did not have this information because Plaintiffs' biostatistician Dr. Madigan did not cite to it (which he did).[1] Dr. Wei ignored the fact that attorneys for the defendants provided him with these documents as well, or failed to notice.

Dr. Wei also largely ignored the NDMA/NDEA dietary and occupational exposure studies that demonstrate a link between NDMA exposure and cancer risk. Rather than address the studies on their merits, he jumped to an unsupported conclusion that virtually all of them are unreliable with no adequate explanation provided. Dr. Wei similarly approached the meta-analysis Dr. Madigan relied on. Dr. Wei insisted that the meta-analysis is unreliable unless a method of best fit analysis was conducted, while simultaneously admitting this analysis is not commonly performed, and he was unable to name a single meta-analysis in which this was conducted.

Dr. Wei also recycled large portions of his previous expert reports, and used his prior reports as a framework for his report in this litigation. He did not adequately consider the issues in this case, and simply switched out a few factual details to tailor his previous reports to this litigation. As a result, he opines on issues that are not pertinent to this case, and does not adequately

[1] Madigan Report (**Exhibit 2**) at 2: "Levels of NDMA in contaminated valsartan tablets range from below the limit of detection to 20.19 μg while levels of NDEA in contaminated valsartan tablets range from below the limit of detection to 1.31 μg.5 Other sources show levels as high as 60.2 μg of NDMA and 5.4 μg of NDEA." He cites to ZHP Exhibit 118 / SOLCO00028261 and TORRENT-MDL2875-00133890 in support.

explain (or understand) several of his opinions, such as lifetime cumulative exposure levels and clinical studies, which are discussed below.

I. THE DAUBERT STANDARD

Federal Rule of Evidence 702, which incorporates the *Daubert* standard, governs the admissibility of expert testimony in Federal Court. The Rule states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the fact of the case.

Fed. R. Evid. 702. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.,* 186 F.3d 412, 417-18 (3d Cir. 1999). "Rule 702 has a liberal policy of admissibility." *Geiss v. Target Corp.,* 2013 *WL* 4675377 at *4 (D.N.J. 2013), citing *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008), other citations omitted. However, an expert still must meet the minimum standards for admissibility. The District of New Jersey has described the following criteria:

> 1) the witness must be an expert (i.e., must be qualified);
> 2) the expert must testify about matters requiring scientific, technical, or specialized knowledge (i.e., must be reliable); and
> 3) the expert's testimony must assist the trier of fact. *Id*.

> A reliable opinion is based on the 'methods and procedures of science rather than on 'subjective belief or unsupported speculation; the expert must have 'good grounds' for his or her belief.… The focus of the reliability inquiry is on the expert's principles and methodology, not on his conclusions…. In determining reliability, a court may look to several non-exhaustive factors, including:
>
> > (1) whether a method consists of a testable hypothesis;
> > (2) whether the method has been subject to peer review;
> > (3) the known or potential rate of error;

> (4) the existence and maintenance of standards controlling the technique's operation;
> (5) whether the method is generally accepted;
> (6) the relationship of the technique to methods which have been established to be reliable;
> (7) the qualifications of the expert witness testifying based on the methodology; and
> (8) the non judicial uses to which the method has been put.
>
> Finally, an opinion fits a particular case (and thus helps the trier of fact) when there is a connection between the scientific research or test result to be presented and particular disputed factual issues in the case…. Fit is an issue of relevance and simply means that scientific validity of the method or principles applies to the issues at hand….

Geiss v. Target Corp., at *4-5, citations omitted. The listed factors are not exhaustive or determinative and must be applied flexibly, emphasizing the "principles and methodology" applied over the actual conclusion reached. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 *U.S.* 579, 595 (1993); *Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999).

However, the Court must still "examine the expert's conclusions in order to determine whether they could reliably flow from the facts known to the expert and the methodology used." *Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 153 (3d Cir. 1999). "But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F.Supp. 2d 587, 595-596 (D.N.J. 2002) citing to *General Elec. Co. v. Joiner*, 522 U.S. at 145–46, 18 S.Ct. 512 (1997). The amendments to Rule 702 make clear that the trial court must evaluate not only the principles and the methodology employed by the expert, but also whether the expert has properly applied those principles and methods to the facts of the case. *See* Fed. R. Evid. 702.

A reliable opinion is "based on 'the methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir.1994)(citing *Daubert*, 509 U.S. at 590). A suggestion or assertion put forth as an opinion based on nothing other than "subject belief and unsupported speculation" makes an opinion unreliable. *See Paoli II*, 35 F.3d at 742-43. "[I]t is the burden of the party offering the expert scientific testimony to demonstrate reliability by a preponderance of the evidence." *In re TMI Litig.*, 193 F.3d 613, 705 (3d Cir. 1999)(citing *Paoli II*, 35 F.3d at 744).

The expert opinion must also fit the issues in the case, i.e., it must be relevant and "assist the trier of fact." *Paoli II*, 35 F.3d at 742–43. The "fit" factor is about relevance. The Advisory Committee, in regard to Rule 702, notes that "[t]he rule accordingly recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts." *See* Notes of Advisory Committee, Fed. R. Evid. 702 (effective Dec. 1, 2011). However, the Advisory Committee adds: "*When opinions are excluded, it is because they are unhelpful and therefore superfluous and a waste of time*." *Id*. (citing 7 Wigmore §1918)(emphasis added).

II. DR. WEI'S OPINIONS SHOULD BE EXCLUDED

1. Dr. Wei's Opinions are Not Generally Accepted in the Scientific Community

a. Dr. Wei's Subjective Epidemiological Study Criteria

"Both an expert's methodology and the application of that methodology must be reviewed for reliability." *In Re: Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d 787, 792 (3rd Cir. 2017), emphasis added. The Court in *Player v. Motiva Enterprises LLC* further defined "reliability," and determined that an expert who failed to consider important facts without satisfactory explanation, among other things, failed the reliability requirement. *Player,* 2006 WL

166452, at *7 (D.N.J. January 20, 2006). The Court held: "His method is untestable and arbitrary, without a generally accepted, established, or peer reviewed methodology, and his evaluation was conducted without any real standards." *Id.* at *8.

Similar to the expert at issue in *Player*, Dr. Wei's opinions fail to meet the reliability requirement of Federal Rule 702, as his literature exclusion method is arbitrary, does not align with any generally accepted methodology, and is not adequately explained. Furthermore, Dr. Wei's methodology was designed to exclude from consideration the scientific data underlying the scientific consensus that NDMA is a probable human carcinogen. In this case, there are numerous epidemiological studies that demonstrate a link between NDMA exposure and an increased risk of cancer. However, Dr. Wei ignored all of them without providing a scientifically satisfactory explanation to justify his exclusion of these studies, which warrants exclusion of his opinion. *Mirena II*, 341 F. Supp. 3d at 242 ("'[A]n expert may not 'pick and choose' from the scientific landscape and present the Court with what he believes the final picture looks like.' Where an expert ignores evidence that is highly relevant to his conclusion, contrary to his own stated methodology, exclusion of the expert's testimony is warranted." (quoting *In re Rezulin Prod. Liab. Litig.,* 309 F. Supp. 2d 531, 563 (S.D.N.Y.2004).

In his report (attached hereto as **Exhibit 3**), Dr. Wei contended that we cannot extrapolate from the NDMA/NDEA dietary and occupational exposure studies due to the "low levels" of NDMA in Valsartan (again, without knowing the levels of NDMA in Valsartan). (Wei Report at 15). Then, in his deposition, Dr. Wei claimed that these studies are not reliable solely because it is not clear whether or not a thorough model fit assessment was conducted. (Wei Dep. (Day 1) 346:4-9). Dr. Wei admitted that he is not aware if this assessment is not something that is commonly done. (Wei Dep (Day 1) 348:16 – 349:1).

Dr. Wei insisted that even if the vast majority of observational studies do not include the sort of comprehensive description of model fit assessment that he demanded, then he would not consider any of those studies to be reliable (Wei. Dep. (Day 1) 349:23 – 350:6). He recognized that this would be a very high standard to require of observational study analyses, but that we, as a society, should strive to do better (and that somehow his refusal to consider observational studies that do not reach his high threshold and are therefore ignored in expert opinions for litigation would somehow make the world a better place). (Wei Dep. (Day 1) 349: 23- 350:12).

Dr. Wei's methodology was created to help him refute solidly supported opinions; he applied virtually unattainable criteria to the literature, and could not adequately explain why he is suddenly insistent on requiring model fit assessments in order for a study to be reliable. His failure to explain the relevant evidence in the NDMA/NDEA dietary and occupational exposure studies warrants exclusion of his opinions. **"[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable**." *In re Zoloft Products Liability Litigation,* 176 F. Supp. 3d 449, 460-61 (E.D. Pa. 2016), citing *In re Rezulin Products Liability Litigation,* 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005), emphasis added. Dr. Wei's consequent failure to evaluate the NDMA/NDEA dietary and occupational exposure literature is of key significance, as these dietary studies are part of the foundation establishing the carcinogenicity of NDMA, and tend to refute his theory to the contrary.[2] Similarly, this literature *was* specifically taken into account by the

[2] *See* Liteplo, R.G., et. al., Concise International Chemical Assessment, N-Nitrosodimethylamine, World Health Organization (WHO), 2002 (**Exhibit 4**). This document cites to and relies on many NDMA/NDEA dietary and occupational exposure studies in support of its finding that NDMA is "highly likely to be a human carcinogen," including several studies the Plaintiffs relied on in Dr. Madigan's report:

- Knekt P, et. al., (1999) Risk of colorectal and other gastro-intestinal cancers after exposure to nitrate, nitrite and *N*-nitroso compounds: a follow-up study (**Exhibit 5**);

Plaintiffs' experts, as it is a critical component of the prevailing scientific consensus that NDMA and NDEA are probable human carcinogens.

Dr. Wei's exclusion of all NDMA/NDEA dietary and occupational exposure studies formulates the basis of his ultimate opinion, and he ignored these studies by applying methodology that is not commonly relied on or generally accepted in his field. Since Dr. Wei provided no scientifically valid explanation for disregarding the NDMA/NDEA dietary and occupational exposure studies that refute his ultimate position, all opinions derived by Dr. Wei are unreliable, and thereby inadmissible. *In re Zoloft Products Liability Litigation,* 176 F. Supp. 3d 449, 460-61 (E.D. Pa. 2016) citing *In re Rezulin Products Liability Litigation,* 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005); *Player v. Motiva Enterprises LLC*, 2006 WL 166452, at *7 (D.N.J. January 20, 2006).

b. Dr. Wei's Unscientific Criticism of Meta-Analyses

Dr. Wei concluded that the meta-analysis of observational studies that Plaintiffs relied on is not sufficient to demonstrate a causal link between NDMA and cancer, claiming it was unclear whether the authors for the individual papers in the meta-analysis checked the adequacy of the models utilized in the analysis. Without this analysis, Dr. Wei claimed all inferences drawn from such peer-reviewed meta-analyses would be [redacted] (Wei Dep. (Day 1) 372:14-15 and Wei Report at 12). However, during his deposition, Dr. Wei acknowledged that this criterion was rarely applied to any meta-analysis of observational studies, and further admitted

- De Stefani, E., et. al., (1996) Dietary nitrosodimethylamine and the risk of lung cancer: a case–control study from Uruguay (**Exhibit 6**);
- Rogers, et. al., (1995) Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper aerodigestive tract cancer (**Exhibit 7**);
- La Vecchia, et. al., (1995) Nitrosamine intake and gastric cancer (**Exhibit 8**).

that he was not aware of a single published meta-analysis that meets his stated criteria -in the course of a largely incomprehensible and evasive response:

[redacted]

[3]

[3] Wei Dep. (Day 1) 374:17- 378:11.

This exchange demonstrates that Dr. Wei is applying a meta-analysis criterion that is not commonly accepted by the community, and is unreasonably restrictive. Moreover, Dr. Wei's responses were so unscientific and combative that they cannot be defended on the basis of sound science: [redacted] (Wei Dep. (Day 1) 381:10-11). These opinions are clearly inadmissible. For the reasons stated above, Dr. Wei's opinion regarding meta-analyses is unreliable and should be excluded.

c. Dr. Wei's Misapplied Criticism of P-Values

Dr. Wei's opinion regarding Dr. Madigan's "improper" reliance on p-values should be excluded under Federal Rule 702 (c), as it is not based on reliable principles and methods. When determining if testimony is the product of reliable principles and data, the Court can consider whether the method is generally accepted in the scientific community. *Geiss v. Target Corp.*, at *4-5, citations omitted. Dr. Wei asserts that Dr. Madigan solely relies on the p-values of various studies to form his opinions regarding the exposure effect of NDMA, and that this is inappropriate. (Wei Report, at 18). In support of his position, Dr. Wei alleges that the American Statistical Association "strongly discourage[s]" the use of p-values of less than .05 to claim statistical significance. (Wei Report, at 6). However, Dr. Herman Gibb, another epidemiologist hired by the Defendants, agrees with Plaintiffs' expert and disagrees with Dr. Wei's assertion:

- [redacted]
- [redacted]

[redacted][4]

Dr. Gibb directly contradicted Dr. Wei's assertion regarding the unreliability of p-values, demonstrating that this principle is not even generally accepted among epidemiologists hired by the Defendants, much less one accepted by the epidemiological community as a whole.

Furthermore, Dr. Wei misunderstood Dr. Madigan's report. When assessing each of the studies provided in his report, Dr. Madigan never draws ultimate conclusions simply because a study demonstrates a statistically significant finding based on p-value, and Dr. Wei could not articulate any instance that suggests Dr. Madigan did this. Dr. Madigan discusses study design, as well as limitations, reports the findings of each study he assessed, and calculates lifetime cumulative exposures of NDMA or NDEA when increased risks are determined in the various studies. (*See* Madigan Report). Simply put, Dr. Madigan was not relying on p-values or statistical significant to draw any ultimate conclusions or 'lines in the sand'. Dr. Wei's opinion regarding p-values is not applicable to Madigan's report, but even if it were, it is not generally accepted, and therefore, not based on reliable principles and methods, and should be excluded.

2. Dr. Wei's Opinions are Unreliable as They are Derived from Preconceived Notions

a. Dr. Wei Copy-and-Pasted Large Sections of his Report from Previous Reports

"An expert should not approach an investigation with **preconceived** notions of results." *Chester Valley Coach Works v. Fisher-Price, Inc.,* 2001 WL 1160012 1, *4 (E.D. Pa. Aug. 29, 2001); *In re Diet Drugs*, MDL 1203, 2001 WL 454586 1, *14 (E.D. Pa. Feb. 1, 2001) (starting with assumptions that a drug causes an adverse event and then attempting to confirm the

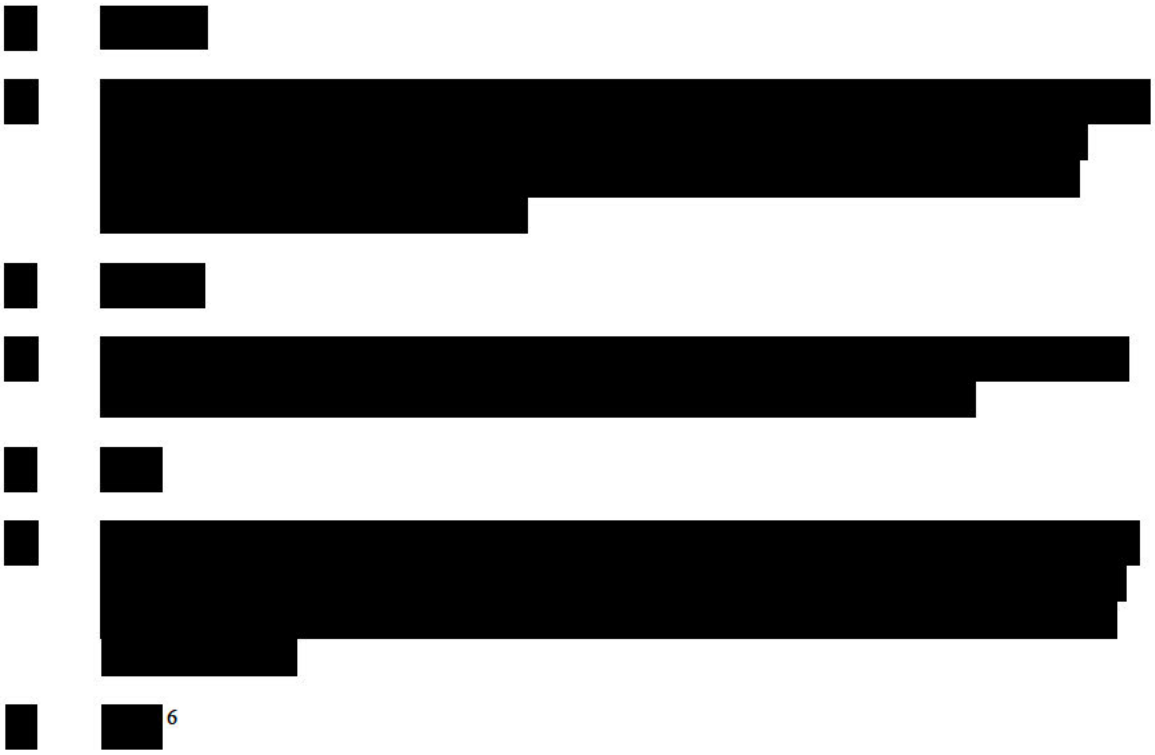
[4] Gibb Dep. (Day 1) 60:12 – 61:5 (**Exhibit 9**).

assumption inverts scientific method, which further undermined the reliability of the expert who applied a subjective methodology); *Caraker v. Sandoz Pharm. Corp.,* 172 F. Supp. 2d 1018, 1049, fn. 5 (S.D. Ill. 2001) ("Justifying a conclusion after the fact by applying a methodology does not generally lead to reliable scientific knowledge."); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)* 341 F. Supp. 3d 213, 241 (S.D.N.Y. 2018) (holding, "[M]ethodology …. aimed at achieving one result … is unreliable, and … must be excluded" (quoting *Faulkner v. Arista Records LLC, 46 F. Supp. 3d 365, 381 (S.D.N.Y. 2014)*).

Dr. Wei reached his opinions before ever reading Dr. Madigan's report. Rather than approaching this litigation with an open-mind, or as a scientist in search of the truth, Dr. Wei simply applied a template to his opinions, and copy-and-pasted large sections of substantive material from reports offered in previous pharmaceutical litigations dating back nearly 15 years ago.[5]

Dr. Wei was also hired to rebut Dr. Madigan in *Taxotere.* In his deposition, Dr. Wei admitted that he reused the "framework" of the *Taxotere* report in his Valsartan report:

[5] See Wei's attached highlighted expert reports from *In re Taxotere Products Liability Litigation* (2019) (**Exhibit 10**) and *In re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation* (2007) (**Exhibit 11**).



[6]

The extensive duplicative language between Dr. Wei's Valsartan report, and reports from previous litigations are discussed for fifty-six pages throughout the first day of the deposition. (Wei Dep. (Day 1) 98-112; 118- 124; 173-209). As demonstrated in the attached highlighted report, Dr. Wei copied a substantial amount of his Valsartan report from his reports from previous litigations, some of which date back as far as nearly fifteen years.

By reading his previous reports in the aforementioned cases, one could predict the outcome of Dr. Wei's "investigation" in this case. Dr. Wei's recycled report demonstrates that from the time he entered this litigation, he applied a framework that is designed to reach a conclusion favorable to the defense. As a result, Dr. Wei looked for and reviewed only the information that would support his ultimate opinion, as explained in previous sections. If this Court finds that Dr.

[6] Wei Deposition (Day 1) 106:24 - 108

Wei formed any of his opinions in this litigation before beginning his research, his opinions should be excluded. Mirena II, 341 F. Supp. 3d at 241 (holding, "Opinions that assume a conclusion and 'reverse-engineer a theory' to fit that conclusion are, similarly, inadmissible").

b. Dr. Wei's Irrelevant Discussion of Clinical Studies

Dr. Wei spends two pages of his report discussing clinical data, though he did not review any such data. (Wei Dep. (Day 1) 79: 7- 80:7). Moreover, Dr. Madigan did not rely on clinical data when formulating his opinion. *See* Madigan Report. Furthermore, the type of "Gold Standard"[7] clinical data sought by Dr. Wei does not exist here because it would not be ethical to construct a randomized, controlled study of the question, which would require one to subject patients to a probable human carcinogen. This was conceded, for example, by ZHP 30(b)(6) witness Min Li, Ph.D., as well as Dr. Wei.:

[redacted]

[redacted][8]

Dr. Wei likely included this discussion in his report because clinical trials were of importance in both the *Taxotere* and *Celebrex* litigations, from which he copied chunks of his *Taxotere* and *Celebrex* expert reports, including the majority of the clinical trials language, and pasted them into the report he submitted in this litigation:

[7] Wei Report, at 10: "For the present case, we cannot utilize such a gold standard approach to evaluate the exposure effect. Thus, observational studies were used for all the articles cited by Dr. Madigan."

[8] Wei Dep. (Day 1) at 114:17 – 115:10.

[redacted][9]

Since clinical trials are not pertinent to this litigation, and Dr. Wei has admittedly not reviewed any clinical trials that pertain to this case, Dr. Wei's testimony regarding clinical trials should be excluded.

c. Dr. Wei's Invalid Opinion Regarding Lifetime Cumulative Exposure Calculations

Dr. Wei criticized Dr. Madigan's Lifetime Cumulative Exposure, hereinafter referred to as "LCE", calculations; however, it is apparent Dr. Wei applied no accepted methodology to provide an opinion on LCEs as he lacked basic, rudimentary knowledge regarding such

[9] Wei Dep. (Day 1) at 197:14 – 199:5. The comparison between Dr. Wei's Valsartan and Celebrex report continues to page 208, line 5.

calculations. An "expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 742 (3d Cir. 1994)* (citations and internal quotations omitted). (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These grounds must support each step of the analysis and, "*any* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible." Allen v. Int'l Bus. Machines Corp.,* CIV.A. 94-264 JJF, 1997 WL 34501372 1, *19 (D. Del. Dec. 18, 1997) citing *In re Paoli R.R. Yard PCB Litig.,* 35 F.3d 717, 745 (3d Cir. 1994)(footnote omitted) (emphasis in original).

Dr. Wei admitted that he has never done his own LCE calculations, even in this case.[10] When asked about Dr. Madigan's calculations, Dr. Wei was unable to provide even an approximate measure of NDMA in Valsartan.[11] Finally, and most damaging, Dr. Wei could not identify or explain key elements of an LCE calculation that go to the heart of Dr. Madigan's

[10] Wei Deposition (Day 1) at 224; lines 11-14: [redacted]

[11] Wei Deposition (Day 1) at 275:7 - 276:6 [redacted]

opinion. In assessing Dr. Madigan's LCE calculation, Dr. Wei did not even know what "ug" stood for, which is the unit of measurement in which Madigan's calculations were conducted:

[redacted][12]

[redacted][13]

Dr. Wei was also unaware of how Dr. Madigan calculated LCEs in this case and unequivocally stated, [redacted] (Wei Deposition (Day 1) 238: 19-20). This lack of specific and general knowledge, and experience, should result in greater scrutiny of the method actually applied by the expert. *See Elcock v. Kmart Corp.*, 233 F.3d 734, 747 (3d Cir. 2000) (quoting *Paoli*, 35 F.3d at 742, n.8).

Dr. Wei's opinion regarding LCEs should also be excluded on the grounds that it will not assist the trier of fact in understanding his testimony, because, as demonstrated above, he is unable

[12] Wei Deposition (Day 1) 219: 5 – 221:6.
[13] Wei Deposition (Day 1) 222: 1 – 24.

to explain his own testimony. Dr. Wei is also lacking sufficient facts or data to support his testimony as he cannot explain even the most basic of principles that pertain to LCEs. Because Dr. Wei lacks virtually all knowledge pertaining to LCE calculations in general or as applied by the plaintiffs' expert he is supposed to be responding to, his opinion regarding Dr. Madigan's calculations, as well as any testimony pertaining to LCEs, should be excluded.

d. Dr. Wei's Lack of Knowledge Regarding the Carcinogenicity of NDMA

In his report, Dr. Wei alleges that "using the results from non-valsartan studies to claim issues for potential carcinogenicity *of low levels of an NDMA impurity* in valsartan is not scientifically valid." (Wei Report at 15). This is a net opinion with no foundation or explanation. When asked about the levels of NDMA in Valsartan during his deposition, Dr. Wei testified that he did not know the levels and had no documents to review that provide the levels. He claimed he was not aware of the amount of NDMA in Valsartan, because Dr. Madigan did not cite to documents that contained this information in his report. (Wei Dep (Day 2) 87:5- 88:18, attached hereto as **Exhibit 12**). However, not only did Dr. Madigan rely on and cite to these documents on page two of his report, the attorneys for the Defendants provided Dr. Wei with the same documents for his review. Dr. Wei chose to ignore the documents, or did not notice that the documents were listed for him by defense counsel on his "Materials Considered" List. (*See* Exhibit B of Dr. Wei's Report at 2).

Dr. Wei's opinion regarding the lack of carcinogenicity of NDMA due to "low levels" in Valsartan should be excluded, as he formed that net opinion without ever reviewing a single document that provided the levels of NDMA in Valsartan. At the time of his deposition, he had no idea how much NDMA was in Valsartan, and he presumably did not know at the time he wrote his report. In so doing, Dr. Wei provided an opinion on behalf of the Defendants that fit his

preconceived notion about the case without relying on any facts or data. Dr. Wei's opinion is unreliable and should be excluded.

CONCLUSION

For the foregoing reasons, Dr. Wei should be precluded from offering his opinions related to general causation, as well as offering any criticisms of Dr. Madigan's report. Dr. Wei's report and opinions are so riddled with problems, that the interim opinions and the ultimate opinion he offered should be deemed unreliable and excluded. Therefore, Dr. Wei's entire opinion, or alternatively, portions of the testimony, should be excluded.

Respectfully,

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Dated: November 1, 2021